UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,796	04/02/2008	H. Lee Sweeney	PENN0870US.NP	8993

26259 7590 05/17/2010

LICATA & TYRRELL P.C.
66 E. MAIN STREET
MARLTON, NJ 08053

EXAMINER	
MELLER, MICHAEL V	
ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
05/17/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No.	Applicant(s)	
	10/566,796	SWEENEY ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/17/07, 2/11/08,5/3/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election **with traverse of muscular dystrophy** in the reply filed on 4/9/2010 is acknowledged. The traversal is on the ground(s) that there are only 4 species and that there is no burden on the examiner to search all of the species. This is not found persuasive because each disease/disorder is completely different from one another. Applicant is reminded that if the examiner does not find the elected species, the examiner will search another one of the species. Art was found on muscular dystrophy thus the species was found.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of treating or preventing skeletal muscle atrophy in a subject comprising administering a bowman-birk inhibitor concentrate or a **derivative thereof**.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims is drawn to a derivative thereof. The specification gives no evidence as to what " **a derivative thereof"** means or what it is. Thus, the claims lack written description. Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed "derivative thereof".

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed (See page 1117). The specification

does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed.” (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of inhibitors, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v.Revel, 25USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only Bowman-Birk inhibitor concentrate, but not the full breadth of the claims (derivative thereof) meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

4. Claims 1-4, 10-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-4, 10-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating skeletal muscle atrophy in a subject comprising administering a bowman-birk inhibitor concentrate does not reasonably provide enablement for **preventing** skeletal muscle atrophy in a subject comprising administering a bowman-birk inhibitor concentrate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art;

With respect to the Wands factors above (particular as they pertain to the quantity of experimentation necessary as well as the state of the prior art within the medical field), Applicants have reasonably demonstrated/disclosed that the claimed composition is useful as a therapeutic agent for treating skeletal muscle atrophy in a subject comprising administering a bowman-birk inhibitor concentrate. However, the claims also encompass using the claimed extract composition to **prevent** such atrophy which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "delaying" (or --treating--), especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to use the instantly claimed composition in a manner so as to provide the functional effect instantly claimed with respect to "preventing" skeletal muscle atrophy in a subject comprising administering a bowman-birk inhibitor concentrate via administering the recited composition to a patient in need thereof .

It is strongly suggested that the phrase "preventing or" be omitted from the claims to overcome the USC 112, first paragraph rejection immediately above in response to this Office action.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term, "or a derivative thereof" is vague and indefinite. What does "derivative" mean anyway ? There is no metes and bounds to this term. It is confusing as to what a derivative of the bowman birk inhibitor concentrate is. Derivative is nowhere defined in the specification and such a term is simply vague and indefinite in its meaning in the art.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Baxter et al. (US 2,596,090).

Baxter teaches that soybean oil contains vitamin E (tocopherol), see col. 1, lines 1-40, col. 2, lines 1-end. It is made clear that vitamin E is obtained from soybean since it is from soybean oil, thus it is a soybean extract and a soybean extract is a Bowman-Birk inhibitor concentrate as defined by applicant's themselves at page 6 of the instant specification. Baxter teaches that the tocopherol is used as a therapeutic agent in the treatment of muscular dystrophy.

All of the claimed methods would be performed when treating muscular dystrophy and anyone having muscular dystrophy will have the claimed symptoms or needs.

9. Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hove et al. and as evidenced by Baxter et al. (US 2,596,090).

Hove teaches that tocopherol (which is a soybean extract for the noted reasons above) is used to treat (cure) muscular dystrophy, see pages 95, 101-102, 105-106. Note that on page 106, it is even stated that the minimum curative dose of tocopherol was 1.1 mg per kilo of body weight per day making it very clear that

muscular dystrophy is indeed treated (cured) by the tocopherol (Vitamin E) and as noted above tocopherol is a soybean extract for the above noted reasons.

Baxter teaches that soybean oil contains vitamin E (tocopherol), see col. 1, lines 1-40, col. 2, lines 1-end. It is made clear that vitamin E is obtained from soybean since it is from soybean oil, thus it is a soybean extract and a soybean extract is a Bowman-Birk inhibitor concentrate as defined by applicant's themselves at page 6 of the instant specification. Baxter teaches that the tocopherol is used as a therapeutic agent in the treatment of muscular dystrophy.

All of the claimed methods would be performed when treating muscular dystrophy and anyone having muscular dystrophy will have the claimed symptoms or needs.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baxter et al. (US 2,596,090).

Baxter teaches that soybean oil contains vitamin E (tocopherol), see col. 1, lines 1-40, col. 2, lines 1-end. It is made clear that vitamin E is obtained from soybean since it is from soybean oil, thus it is a soybean extract and a soybean extract is a Bowman-Birk inhibitor concentrate as defined by applicant's themselves at page 6 of the instant specification. Baxter teaches that the tocopherol is used as a therapeutic agent in the treatment of muscular dystrophy.

In the event it is seen that the vitamin E in Baxter is not from soybean (which this examiner does not agree with) then it would have been obvious at the time the invention was made to use a soybean extract containing vitamin E since vitamin E (tocopherol) is well known to be in soybeans (Baxter confirms this) to treat muscular dystrophy since Baxter teaches that vitamin E is known to be used to treat muscular dystrophy. Since soybeans are a well known source of vitamin e then it clearly would have been obvious to use a soybean extract since it is known to contain vitamin e which is known to treat muscular dystrophy according to Baxter.

All of the claimed methods would be performed when treating muscular dystrophy and anyone having muscular dystrophy will have the claimed symptoms or needs.

12. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hove et al. in view of Baxter et al. (US 2,596,090).

Hove teaches that tocopherol (which is a soybean extract for the noted reasons above) is used to treat (cure) muscular dystrophy, see pages 95, 101-102, 105-106. Note that on page 106, it is even stated that the minimum curative dose of tocopherol was 1.1 mg per kilo of body weight per day making it very clear that muscular dystrophy is indeed treated by the tocopherol (Vitamin E) and as noted above tocopherol is a soybean extract for the above noted reasons.

Baxter teaches that soybean oil contains vitamin E (tocopherol), see col. 1, lines 1-40, col. 2, lines 1-end. It is made clear that vitamin E is obtained from soybean since it is from soybean oil, thus it is a soybean extract and a soybean extract is a Bowman-Birk inhibitor concentrate as defined by applicant's themselves at page 6 of the instant specification. Baxter teaches that the tocopherol is used as a therapeutic agent in the treatment of muscular dystrophy.

In the event it is seen that the vitamin E in Hove is not from soybean (which this examiner does not agree with) then it would have been obvious at the time the invention was made to use a soybean extract containing vitamin E since vitamin E (tocopherol) is well known to be in soybeans (Baxter confirms this) to treat muscular dystrophy since Hove and Baxter teach that vitamin E is known to be used to treat (cure) muscular dystrophy. Since the Bowman Birk inhibitor concentrate is a soybean extract (as noted by applicants at page 6 in the specification) which is what Vitamin E is, then clearly it does not matter where the vitamin E comes from (since it is still a soybean extract since soybeans have Vitamin E in them) as long as it is vitamin E which is clearly taught in Hove. Since soybeans are a well known source of vitamin e then it clearly would have been obvious to use a soybean extract since it is known to contain vitamin e which is known to treat muscular dystrophy according to both Baxter and Hove.

All of the claimed methods would be performed when treating muscular dystrophy and anyone having muscular dystrophy will have the claimed symptoms or needs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael V. Meller
Primary Examiner
Art Unit 1655

/Michael V. Meller/
Primary Examiner, Art Unit 1655